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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,951	01/29/2002	Paul A. Moore	PF378PID1	4875
22195	7590	12/03/2003	EXAMINER	
HUMAN GENOME SCIENCES INC			HADDAD, MAHER M	
9410 KEY WEST AVENUE			ART UNIT	
ROCKVILLE, MD 20850			PAPER NUMBER	

1644

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/057,951	<b>Applicant(s)</b> MOORE ET AL.	
	<b>Examiner</b> Maher M. Haddad	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-25, 28-51, 54-84, 87-110, 113-119 and 122-198 is/are pending in the application.  
     4a) Of the above claim(s) 45-46, 79, 104-105 and 138 is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Continuation of Disposition of Claims:

Claims allowed are 21-25, 28-29,32,38-40,42,43,56-60,63,64,66,72-74,76,77,80-84,87,88,91,97-99,101,102,115-119,122,123,125,131-133,135,136,139,142-157,160,166-173,176,182-188 and 194-198.

Continuation of Disposition of Claims:

Claims rejected are 30,31,33-37,41,44,47-51,54,55,65,67-71,75,78,89,90,92-96,100,103,106-110,113,114,124,126-130,134,137,140,141,158,159,161-165,174,175,177-181 and 189-193.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 8/4/03, is acknowledged.
2. Claims 21-25, 28-51, 54-84, 87-110, 113-119, 122-198 are pending.
3. Claims 45-46, 79, 104-105 and 138 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claims 21-25, 28-44, 47-51, 54-78, 80-84, 87-103, 106-110, 113-119, 122-137 and 139-198 are under examination as they read on an antibody or fragment thereof that specifically binds to t-PALP.
5. The following is a quotation of the second paragraph of 35 U.S.C. 112.  
*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*
6. Claims 30, 31, 33-37, 41, 44, 47-51, 54-55, 65, 67-71, 75, 78, 89-90, 92-96, 100, 103, 106-110, 113-114, 124, 126-130, 134, 137, 140-141, 158-159, 161-165, 174-175, 177-181 and 189-193 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A. The "fragment thereof" which is a human antibody in claims 30, 65, 89, 124, 141 and 158 is ambiguous and indefinite because only intact antibody can be a human antibody and not an antibody fragment. It is suggested that said claims be amended to recite, for example "The antibody or fragment thereof of claim 23, wherein the antibody is a human antibody" (claim 30).
  - B. The "fragment thereof" which is a polyclonal antibody in claims 31, 90, 159 and 174 is ambiguous and indefinite because only antibody can be a polyclonal antibody and not an antibody fragment. It is suggested that the claims be amended to recite, for example "The antibody or fragment thereof of claim 23, wherein the antibody is a polyclonal antibody" (claim 31).
  - C. The "fragment thereof" which is a monoclonal antibody in claims 54, 113, 140 and 175 is ambiguous and indefinite because only antibody can be a monoclonal antibody and not an antibody fragment. It is suggested that the claims be amended to recite, for example "The antibody or fragment thereof of claim 47, wherein the antibody is a monoclonal antibody" (claim 54).

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- D. The “fragment thereof” in claims 44, 78, 103 and 137 is indefinite and ambiguous because hybridoma does not produce antibody fragment, hybridoma produce only a whole intact antibody. It is suggested that the claims be amended to recite, for example
- i. “The antibody or fragment thereof of claim 23, wherein the antibody is produced by a hybridoma” (claim 44) or
  - ii. “A hybridoma that produces the antibody of claim 23” (claim 44).
- E. The “fragment thereof” in claims 47, 106, 189-193 is indefinite and ambiguous because only antibody, not antibody fragment, can be obtained from animal that has been immunized with a protein. It is suggested that the claims be amended to recite, for example “An isolated antibody or fragment thereof, wherein the antibody is obtained from ...” (claim 47).
- F. Claims 33-37, 67-71, 92-96, 126-130, 161-165 and 177-181 have no antecedent basis in base claims 23, 58, 82, 117, 145 and 168, respectively, because claims 23, 58, 82, 117, 145 and 168 recite antibody or fragment thereof per se, whereas a labeled antibody or fragment thereof is recited in claims 33-37, 67-71, 92-96, 126-130, 161-165 and 177-181. It is suggested that claims 33-37, 67-71, 92-96, 126-130, 161-165 and 177-181 be changed to “A labeled antibody or fragment thereof, wherein the antibody or fragment thereof of claim (23, 58, 82, 117, 145 or 168) is labeled” and dependent claims thereof be changed to “The labeled antibody or fragment thereof of claim ...”.
- G. Claims 41, 75, 100 and 134 have no antecedent basis in base claims 23, 58, 82 and 117, respectively, because claims 23, 58, 82 and 117 recite antibody or fragment thereof per se, whereas a fusion antibody or fragment thereof is recited in claims 41, 75, 100 and 134. It is suggested that the claims be amended to recite, for example “A fused antibody or fragment thereof, wherein the antibody or fragment thereof of claim 23 is fused to a heterologous polypeptide” (claim 41).
7. Claims 21-25, 28-29, 32, 38-40, 42-43, 56-60, 63-64, 66, 72-74, 76-77, 80-84, 87-88, 91, 97-99, 101-102, 115-119, 122-123, 125, 131-133, 135-136, 139, 142-157, 160, 166-173, 176, 182-188 and 194-198 are allowable.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner’s voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.  
Patent Examiner  
Technology Center 1600  
November 28, 2003

  
**CHRISTINA CHAN**  
**SUPERVISORY PATENT EXAMINER**  
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